

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-4, 6-8, 41 and 72-81 are pending in the application, with claims 1 and 73 being the independent claims. Claims 1, 72 and 73 are sought to be amended. New claims 74-81 are sought to be added. Support for the amendments and new claims can be found throughout the specification and in the original and previously presented claims. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***I. Rejections Under 35 U.S.C. § 112, Second Paragraph***

***Claims 1-4, 6-8, 41, 72 and 73***

Claims 1-4, 6-8, 41, 72 and 73 are rejected under 35 U.S.C. § 112, second paragraph. Office Action, page 2, lines 16-18. In particular, the Examiner alleges that

Claims 1 and 73 are rejected as vague and indefinite because it is unclear whether "one or more nucleic acid molecules" in step ii) of the claims are identical to "one or more double stranded nucleic acids" in step i) of the claims or not. Please clarify.

Claim 72 is rejected as vague and indefinite because it is unclear that said one or more nucleic acid molecules recited in claim 72 is said one or more double stranded nucleic acid molecules or said one or more single stranded nucleic acid molecules as recited in claim 1. Note that claim 1 has double stranded nucleic acid molecules and single stranded nucleic acid molecules. Please clarify.

Office Action, page 2, line 19 to page 3, line 3.

Solely to expedite prosecution and not in acquiescence to the rejection, Applicants have distinguished "*additional* nucleic acid molecules" and "*target* nucleic acid molecules" from other nucleic acid molecules described in the claims. It is believed that these distinguishing recitations clarify claims 1, 72 and 73. Accordingly, Applicants respectfully request that the examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, Second Paragraph.

## ***II. Rejections Under 35 U.S.C. § 102(b)***

### ***Claims 1, 2, 4, 6 and 41***

Claims 1, 2, 4, 6 and 41 are rejected under 35 U.S.C. § 102(b). Office Action, page 3, paragraph 7. In particular, the Examiner alleges that the claims are "anticipated by Allison *et al.*, (US Patent No. 5,650,167, published on July 22, 1997) as evidence[d] by Inman *et al.*, (J. Mol. Biol., 49, 93-98, 1970)." Office Action, page 3, paragraph 7. In particular, the Examiner alleges that

Allison *et al.*[ ] teach to denature viral nucleic acids in a supernatant fluid from monolayer culture in 96 well plates with 1 M NaOH and then load neutralized viral nucleic acids in the supernatant fluid to a nylon membrane. The viral nucleic acids on the membrane are crosslinked to the membrane by UV light and hybridized with HBV DNA in the presence of Denhardt's solution containing 1% glycine (see column 11, last paragraph and column 12, first paragraph). Since it is known that NaOH only partially denatures a double stranded DNA (see Inman *et al.*, abstract in page 93, fifth paragraph in page 94, and first paragraph in page 97), the viral nucleic acids on the membrane taught by Allison *et al.*, contain both single stranded and double stranded viral nucleic acids. . . . Since Allison *et al.*, teach to hybridize the viral nucleic acids on the membrane (containing double stranded nucleic acids) with the HBV DNA in the presence of Denhardt's solution containing 1% glycine, Allison *et al.*, disclose contacting one or more double-stranded nucleic acid molecules (ie., the viral nucleic acids containing double stranded nucleic acids on the membrane) with an amino acid denaturant (ie., glycine) thereby forming one or more single-stranded nucleic acid molecules (ie., single stranded viral nucleic acids in the membrane and in the Denhardt's solution) and combining said one or more single-stranded nucleic acid

molecules with one or more nucleic acid molecules wherein said one or more nucleic acid molecules (ie., the HBV DNA) are capable of hybridizing to said single-stranded nucleic acid molecules thereby obtaining one or more of said hybridized nucleic acid molecules as recited in claim 1. Since Allison *et al.*, teach glycine and it is known that glycine is a natural amino acid or an amino acid denaturant, claims 2, 4, and 41 are anticipated by Allison *et al.*[]

Regarding claim 6, since 1% glycine is equal to a concentration of about 135 mM glycine, claim 6 is anticipated by Allison *et al.*[]

Therefore, Allison *et al.*, teach all limitations recited in claims 1, 2, 4, 6, and 41.

*Id.*, at page 3, line 15, through page 4, line 17. Applicants respectfully traverse the rejection.

For a reference to be anticipatory under 35 U.S.C. § 102(b), it must teach every element of the claim. *See* M.P.E.P., 8<sup>th</sup> ed., § 2131 (Rev. 2, May 2004). However, the "inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 . . . ." *Id.* at § 2112. The M.P.E.P. provides guidance to examiners regarding what is required to make out a *prima facie* case for an inherency-based rejection:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

...

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

*Id.* at "IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY" (emphasis in original). Hence, for an inherency-based rejection under 35 U.S.C. § 102(b) to be proper, the allegedly inherent result or characteristic must be shown to actually exist. It is not sufficient to merely allege its probability or possibility.

Here, the Examiner has improperly relied upon Inman *et al.* to assert that NaOH (as used by Allison *et al.* in Example 1) only partially denatures HBV DNA. The Examiner's presumption is incorrect. It is noted that Allison *et al.* indicates that the "[s]upernatant fluid [containing HBV DNA] . . . was denatured with 20 µL 1M NaOH . . . ." Column 11, lines 58-59. However, Allison *et al.* does not teach or suggest that this DNA is only partially denatured, and Inman *et al.* does not cure this deficiency. Inman *et al.* is limited to a description of the denaturation of  $\lambda$ DNA. Moreover, Inman *et al.* found that  $\lambda$ DNA was only partially denatured by NaOH *because of its rich GC regions*:

For example, after 308 minutes at pH 11.29 (Fig. 2(c)) the right half is almost completely denatured but two small regions can be observed which remain undenatured (12.9 µ and 15.7 µ). It can be concluded, therefore, that these two positions represent the G-C-richest regions on the right half of the  $\lambda$  DNA molecule.

Inman *et al.*, page 97, last two sentences of first full paragraph.

In contrast, Allison *et al.* is denaturing HBV DNA. HBV DNA and  $\lambda$ DNA have different properties and would be expected by the skilled artisan to behave differently in

alkaline conditions. Hence, absent a showing that HBV DNA has rich GC regions similar to  $\lambda$ DNA, the skilled artisan would have no reason to believe that Allison *et al.*'s exposure of HBV DNA to NaOH results in only partially denatured HBV DNA. Rather, the skilled artisan upon reading Allison *et al.*'s Example 1 would presume that the HBV DNA is completely denatured by NaOH. Moreover, there is no teaching or suggestion to the skilled artisan that the use of glycine in this Example is for the purpose of denaturing double-stranded HBV DNA.

Because a reference is only anticipatory when it teaches each and every element of a claim, and because a *prima facie* case has not been made that Allison *et al.* teaches denaturing DNA with glycine, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 2, 4, 6 and 41 under 35 U.S.C. § 102(b).

### ***III. Rejections Under 35 U.S.C. § 103(a)***

#### ***A. Claims 1, 2, 4, 6-8 and 41 Over Zarling et al. in View of Aslanyan et al.***

Claims 1, 2, 4, 6-8 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* (U.S. Patent No. 5,719,023) in view of Aslanyan *et al.* (*Biophys.*, 29: 615-620 (1984)). Office Action, page 5, beginning at line 9. In particular, the Examiner alleges that

. . . it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed a hybridization assay using a single stranded nucleic acid probe denatured by an amino acid denaturant in view of the prior art of Zarling *et al.*, and Aslanyan *et al.* One having ordinary skill in the art would have been motivated to do so because Aslanyan *et al.*, have successfully used an amino acid denaturant (ie., glycine) to denature a double stranded nucleic acid probe into a single stranded nucleic acid probe and the simple replacement of one well known denaturation method (i.e., heat denaturation taught by Zarling *et al.*) from another well known

denaturation method (i.e., denaturation by an amino acid denaturant taught by Aslanyan *et al.*[]) during the process of a hybridization assay would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because heat denaturation taught by Zarling *et al.*, and denaturation by an amino acid denaturant taught by Aslanyan *et al.*[], are functional equivalent methods which are used for the same purpose.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06.

Office Action, page 6, line 17, through page 7, line 11. Applicants respectfully traverse the rejection.

The Examiner's reliance upon M.P.E.P. § 2144.06 is misplaced because the requirements for establishing a *prima facie* case of obviousness under 35 U.S.C. §103 have not been met. The Examiner bears the initial burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *See* M.P.E.P., 8<sup>th</sup> ed., § 2142 (Rev. 2, May 2004). Amongst the requirements for setting forth a *prima facie* case, the Examiner must show "some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." *Id.* M.P.E.P. § 2144.06 is neither a substitute for or satisfaction of this requirement.

Rather, the judicial decisions discussed in M.P.E.P. § 2144.06 reflect the need for satisfaction of this requirement. Furthermore, these decisions support Applicants' assertion that a *prima facie* case of obviousness has not been established. In particular, the court in *In re Scott* disagreed with "[t]he examiner and the board . . . [for holding] that the mere existence of 'functional and mechanical equivalence' establishes

'obviousness.'" *In re Scott*, 139 USPQ 297, 299 (C.C.P.A. 1963). The court continued by explaining the irrelevance of mere functional equivalence and the requirements under 35 U.S.C. § 103:

We think this involves a non-sequitur. Expedients which are functionally equivalent to each other are not necessarily obvious *in view of* one another. The statutory mandate of 35 U.S.C. 103 is that the claimed subject matter be unobvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

...

The rejection, in our opinion, is based upon an improper hindsight view of the art after having full benefit of appellant's disclosure.

*Id.* at 299-300. The *Scott* court reversed the functional equivalence-based obviousness rejection because functional equivalence alone is not sufficient to show the requisite suggestion or motivation.

The insufficiency of mere functional equivalency for obviousness purposes was also described by the court in *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987). In that case, despite "prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art," the *Geiger* court overturned the Board of Patent Appeals and Interferences' holding that "it would have been prima facie obvious, within the meaning of 35 U.S.C. § 103, to employ these components in combination for their known functions . . . ." *Id.* at 1277-1278. The *Geiger* court found that mere functional equivalency and known use in the art was an insufficient basis for a rejection under 35 U.S.C. § 103 because "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." *Id.* at 1278 (citing *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). Hence, these cases and the M.P.E.P. make clear that

even if components constitute well known functional equivalents, their substitution *is not obvious* absent some teaching or suggestion in the art.

In setting forth the present rejection, the Examiner has done no more than allege that it would be obvious to substitute functionally equivalent components which are described in separate documents. Applicants respectfully assert that such a lone allegation is contrary to judicial decisions and the M.P.E.P. as described above. Applicants also wholly incorporate herein the arguments made at pages 9-11 in the Amendment and Reply Under 37 C.F.R. § 1.116 filed on August 29, 2003, and respectfully assert that the references cited in support of the 35 U.S.C. § 103 rejection do not establish a *prima facie* case of obviousness.

Hence, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 2, 4, 6-8 and 41 under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* in view of Aslanyan *et al.*

***B. Claims 1-3 and 41 Over Zarling et al. in View of Yoshida***

Claims 1-3 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* in view of Yoshida (*Biochem. Biophys. Res. Comm.*, 116: 217-221 (1983)). Office Action, page 9, starting at section 10. In particular, the Examiner alleges that

. . . it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed a hybridization assay using a single stranded nucleic acid probe denatured by an amino acid denaturant comprising polyamino acids in view of the prior art of Zarling *et al.*, and Yoshida. One having ordinary skill in the art would have been motivated to do so because Yoshida has successfully used an amino acid denaturant (i.e., poly-L-glutamic acid) to denature a double stranded nucleic acid probe into a single stranded nucleic acid probe and the simple replacement of one well known denaturation method (i.e., heat denaturation taught by Zarling *et al.*) from another well known



denaturation method (i.e., denaturation by an amino acid denaturant taught by Yoshida) during the process of a hybridization assay would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because heat denaturation taught by Zarling *et al.*, and denaturation by an amino acid denaturant taught by Yoshida are functional equivalent methods which are used for the same purpose.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06.

Office Action, page 10, lines 1-19. Applicants respectfully traverse the rejection.

As in the rejection of section III.A. above, the Examiner's reliance upon M.P.E.P. § 2144.06 is misplaced because the requirements for establishing a *prima facie* case of obviousness under 35 U.S.C. §103 have not been met. In setting forth the present rejection, the Examiner has done no more than allege that it would be obvious to substitute functionally equivalent components which are described in separate documents. Applicants wholly incorporate the arguments made in section III.A. above, and respectfully assert that the rejection is contrary to judicial decisions and the M.P.E.P. Applicants also wholly incorporate herein the arguments made at pages 11-13 in the Amendment and Reply Under 37 C.F.R. § 1.116 filed on August 29, 2003, and respectfully assert that the references cited in support of the 35 U.S.C. § 103 rejection do not establish a *prima facie* case of obviousness.

Hence, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-3 and 41 under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* in view of Yoshida.

**C. Claims 6-8 Over Zarling *et al.* in View of Yoshida**

Claims 6-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* in view of Yoshida. Office Action, page 12, starting at section 11. In particular, the Examiner alleges that

. . . it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used an amino acid denaturant with different concentrations in the method as recited in claim 1 in view of prior art of Zarling *et al.*, and Yoshida. One having ordinary skill in the art has been motivated to do so because optimization of concentration of an amino acid denaturant during the process of denaturing a double stranded nucleic acid would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have . . . [had] a reasonable expectation of success to optimize concentration of an amino acid denaturant during the process of denaturing a double stranded nucleic acid. Note that, where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (see MPEP 2144.05).

Office Action, page 13, lines 6-19. Applicants respectfully traverse the rejection.

Applicants note that this rejection is an extension of the rejection described in section **III.B.** above, with further reliance upon M.P.E.P. § 2144.05. However, as already described in section **III.B.**, the rejection of claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* in view of Yoshida should be withdrawn as being contrary to judicial decisions and the M.P.E.P. Applicants also wholly incorporate by reference the arguments made at pages 13-14 in the Amendment and Reply Under 37 C.F.R. § 1.116 filed on August 29, 2003, and respectfully assert that the references cited in support of the 35 U.S.C. § 103 rejection do not establish a *prima facie* case of obviousness.

Hence, because claims 6-8 ultimately depend upon claim 1, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Zarling *et al.* in view of Yoshida.

***D. Claims 7 and 8 Over Allison et al. as Evidenced by Inman et al.***

Claims 7 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Allison *et al.* as evidenced by Inman *et al.*, as applied to claims 1, 2, 4, 6 and 41 above. Office Action, page 16, beginning at line 1. Although the Examiner acknowledges that neither of these documents teaches the concentration of amino acid denaturant as recited in the claims, the rejection alleges that

. . . it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used an amino acid denaturant with different concentrations in the method as recited in claim 1 in view of prior art of Allison *et al.*, as evidence[d] by Inman *et al.*[] One having ordinary skill in the art has been motivated to do so because optimization of concentration of an amino acid denaturant during the process of denaturing a double stranded nucleic acid would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have . . . [had] a reasonable expectation of success to optimize concentration of an amino acid denaturant during the process of denaturing a double stranded nucleic acid. Note that, where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (see MPEP 2144.05).

Office Action, page 16, lines 9-22. Applicants respectfully traverse the rejection.

Applicants note that this rejection is an extension of the rejection described in section II. above, with further reliance upon M.P.E.P. § 2144.05. However, as already described in section II., the rejection of claim 1 under 35 U.S.C. § 102(b) as being

unpatentable over Allison *et al.* as evidenced by Inman *et al.* should be withdrawn for failure to teach each and every element of the claim. Furthermore, the Examiner has not indicated how claim 1 is obvious over Allison *et al.* as evidenced by Inman *et al.*

Hence, because claims 7 and 8 ultimately depend upon claim 1, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 7 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Allison *et al.* as evidenced by Inman *et al.*

***E. Claims 1, 2, 4, 6-8, 41, 72 and 73 Over Mitchell et al. in View of Aslanyan et al.***

Claims 1, 2, 4, 6-8, 41, 72 and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mitchell *et al.* (*Anal. Biochem.*, 178: 239-242 (1989)) in view of Aslanyan *et al.* Office Action, page 17, beginning at line 1. In particular, the Examiner alleges that

... it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed a hybridization assay recited in claims 1 and 73 using a non-haptenylated single stranded nucleic acid probe denatured by an amino acid denaturant in view of the prior art of Mitchell *et al.*, and Aslanyan *et al.* One having ordinary skill in the art would have been motivated to do so because Aslanyan *et al.*, have successfully used an amino acid denaturant (ie., glycine) to denature a double stranded nucleic acid probe into a single stranded nucleic acid probe and the simple replacement of one well known denaturation method (i.e., NaOH denaturation taught by Mitchell *et al.*) from another well known denaturation method (i.e., denaturation by an amino acid denaturant taught by Aslanyan *et al.*), during the process of a hybridization assay would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because NaOH denaturation taught by Mitchell *et al.*, and denaturation by an amino acid denaturant taught by Aslanyan *et al.*, are functional[ly] equivalent methods which are used for the same purpose.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their

expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06.

Office Action, page 19, line 16, through page 20, line 11. Applicants respectfully traverse the rejection.

As in the rejection of section **III.A.** above, the Examiner's reliance upon M.P.E.P. § 2144.06 is misplaced because the requirements for establishing a *prima facie* case of obviousness under 35 U.S.C. §103 have not been met. In setting forth the present rejection, the Examiner has done no more than allege that it would be obvious to substitute functionally equivalent components which are described in separate documents. Applicants wholly incorporate the arguments made in section **III.A.** above, and respectfully assert that the rejection is contrary to judicial decisions and the M.P.E.P. Applicants respectfully assert that the references cited in support of the 35 U.S.C. § 103 rejection do not establish a *prima facie* case of obviousness.

Hence, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 2, 4, 6-8, 41, 72 and 73 under 35 U.S.C. § 103(a) as being unpatentable over Mitchell *et al.* in view of Aslanyan *et al.*

***IV. Non-Statutory Double Patenting Rejection***

***Claims 1-4, 6-8, 41 and 72***

Claims 1-4, 6-8, 41 and 72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Pat. No. 6,268,133 in view of Zarling *et al.* See Office Action, page 21, beginning at line 1. In particular, the Examiner alleges that

. . . it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed a hybridization assay using a single stranded nucleic acid probe denatured by an amino acid denaturant in view of U.S. Patent No. 6,268,133 and the prior art of Zarling *et al.*[] One having ordinary skill in the art would have been motivated to do so because Zarling *et al.*, has successfully used a single stranded nucleic acid probe produced by denaturation for a hybridization assay and use of a single stranded nucleic acid for different assays such as a hybridization assay would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have . . . [had] a reasonable expectation of success to use a single stranded nucleic acid probe denatured by an amino acid denaturant for a hybridization assay.

Office Action, page 21, lines 12-23. Applicants respectfully traverse the rejection.

Applicants thank the Examiner for pointing out that "[a] timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application."

Office Action, page 20, second to last paragraph.

Applicants respectfully request reconsideration and withdrawal of the Double Patenting Rejection. However, in the event that the Examiner is unwilling to reconsider and withdraw this rejection, Applicants respectfully request that the Examiner hold this Double Patenting Rejection in abeyance until all other rejections are withdrawn.

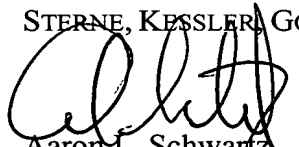
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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